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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/562,345	02/07/2006	Dennis Heemskerk	ES/4662-116	4007

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EXAMINER	
BERCH, MARK L	

ART UNIT	PAPER NUMBER
1624	

MAIL DATE	DELIVERY MODE
02/26/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/562,345	HEEMSKERK ET AL.	
	Examiner	Art Unit	
	/Mark L. Berch/	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 December 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7,11,12,15 and 17-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,11,12,15 and 17-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The rejections over WO 97/04086, WO 96/02663 and 4073687 were overcome by amendment to claim 1.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-7, 11-12, 15, 17, 19-21, 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 99/31109.

The reference was discussed previously. There are only two cephalosporins taught, cephradine and cefaclor. The actual working example happens to make cefaclor, but it would be obvious to do the same thing with cephradine since it is the only other one taught. Note that it is done at 10°C and pH=7.0. Yields were 84.6% and >90%. The reference does employ naphthol additives, but the claims are open-ended ("comprising...") and hence are embracive of using such additives in the acylation process as seen in Example IV of the reference.

The traverse is unpersuasive. Applicants argue that this is a manufacture of complexes. However, Example IV, with yields of 84.6% and >90%, is an enzymatic synthesis example, not a complexing example as is seen in e.g. Example III. Applicants

argue that this is cefaclor, not cephradine, but that just means that the reference is not an anticipation. It is obvious for cephradine for reasons set forth above. As for the temperature, the fact remains, it was done at 10°C. The fact that there is also taught a broader temperature range, some of which is outside the claim 1 language, is beside the point. The reference only need teach doing it at 10°C; it does not need to appreciate the advantage of that temperature, nor does it need to teach a different temperature for a different type of enzyme. So long as it meets one branch of the claim, it renders the claim obvious.

Claim Rejections - 35 USC § 112

> The following is a quotation of the first paragraph of 35 U.S.C. 112:
>
> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
>
> The following is a quotation of the second paragraph of 35 U.S.C. 112:
>
> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-7, 11-12, 15, 17-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1. The 15□ inserted into claim 4 is in error. Claim 1 does not permit 15□ itself, since it says "below...".

2. Claim 29 is unduly functional, as it does not say what the pH and temperature is. pH and temperature can be precisely defined by numbers, and this must be done. The traverse is unpersuasive. The amendment to claim 1 has nothing to do with this. First, pH is not mentioned in claim 1. Second the temperature here is for the crystallizing process, which takes place after the reaction.
3. In claim 1, the "concentration ... in the reaction mixture is below 2%" has two possible meanings. It could be met by being below 2% the entire time, or it could be met by being below 2% for just some part of the time. The traverse is unpersuasive. The amendment to claim 1 does not deal with this issue.
4. The S/H limitation, originally in claim 13 is unclear but now imported into claim 1 is unclear. The S/H ratio does not depend just on the enzyme, but also on the conditions e.g. temperature and pH employed, concentration and relative amounts of the two reactants. Suppose that the enzyme was better under some conditions but not others? The claim treats the S/H value as an intrinsic characteristic of the enzyme, but it is not.
5. The 0% in claim 22 makes no sense. If there is no 7-ADCA present, the reaction cannot take place. The traverse is unpersuasive. Ranges include their endpoints. See e.g. ***In re Malagari***, 182 USPQ 549, in which the claim range of "between 0.03 and 0.07% carbon" and a prior art range of .020-.030 are referred to as a range which "touches". See also ***Ex parte Lee***, 31 USPQ2d 1105.

Claims 19-21, 23 and 29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to

which it pertains, or with which it is most nearly connected, to make and/or use the invention.

As written, these are a process for crystallizing cephradine, but in fact, it is the monohydrate which is actually crystallized.

Claims 24-26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claim says "hydrate" but in fact, cephradine forms both a monohydrate and a dihydrate, but Example III here produced only the monohydrate. Applicants have not demonstrated that this process produces both hydrates, and it would be surprising if it did.

The traverse is unpersuasive. Applicants state "other hydration states can be made". That may or may not be true, but is beside the point. The question is whether applicants process actually does that. In the actual example 3, it is only the monohydrate which is formed. If applicants can demonstrate that the trihydrate can be formed under the conditions of claim 24, then the rejection will be overcome. But if not, then the claim cannot be deemed enabled.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed

until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to /Mark L. Berch/ whose telephone number is 571-272-0663. The examiner can normally be reached on M-F 7:15 - 3:45.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on (571)272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mark L. Berch/
Primary Examiner
Art Unit 1624

2/26/2009